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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,975	03/30/2005	Sonal Patel	2543-1-036PCT/US	3823

23565 7590 11/08/2006

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EXAMINER	
LOCKARD, JON MCCLELLAND	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,975	PATEL, SONAL	
	Examiner	Art Unit	
	Jon M. Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignment*.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 5, 13-15, 17, and 20, drawn to methods of diagnosis comprising detecting/quantifying SC6 *polypeptide* in a biological sample.

Group II, claim(s) 2, 16, and 19, drawn to methods of diagnosis comprising detecting/quantifying SC6 *nucleic acid* in a biological sample.

Group III, claim(s) 3-4, drawn to antibodies that bind an SC6 polypeptide.

Group IV, claim(s) 6-8 (in part), in so far as they are drawn to a method for screening agents that modulate the activity of an SC6 polypeptide.

Group V, claim(s) 6 and 8 (in part), in so far as they are drawn to a method for screening agents that modulate the expression of an SC6 polynucleotide or polypeptide.

Group VI, claim 8 (in part), in so far as it is drawn to an agent of undisclosed constitution that inhibits or down-regulates the activity of an SC6 polypeptide.

Group VII, claim 8 (in part), in so far as it is drawn to an agent of undisclosed constitution that inhibits or down-regulates the expression of an SC6 polynucleotide or polypeptide.

Group VIII, claim(s) 10, 18, and 21 (in part), in so far as they are drawn to methods of treatment comprising administering an SC6 polypeptide.

Group IX, claim(s) 10, 18, and 21 (in part), in so far as they are drawn to methods of treatment comprising administering an SC6 polynucleotide.

Group X, claim(s) 10, 18, and 21 (in part), in so far as they are drawn to methods of treatment comprising administering an agent which inhibits or down-regulates the expression of an SC6 polypeptide.

Group XI, claim(s) 10, 13, 18, and 21 (in part), in so far as they are drawn to methods of treatment comprising administering an agent which inhibits or down-regulates the activity of an SC6 polypeptide.

2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a method of detecting and/or quantifying an SC6 polypeptide (or fragments or variants thereof) in a biological sample. However, since Sanjanwala et al. (WO 01/090148, published 29 November 2001; reference BD on IDS filed 25 April 2005) neurotransmitter polypeptide (NTT-4; SEQ ID NO:4) that shares 98% sequence identity to the SCN6 polypeptide (SEQ ID NO:1) of the instant invention (see attached sequence alignment), as well as methods for detecting/quantifying the polypeptide in a biological sample (see for example claim 29), no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Groups II-XI inventions are not present in the Group I claims, unity of invention is lacking. Furthermore, the methods of Groups I-II, IV-V, and VIII-XI are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other. Lastly, the antibodies of Group III, the agents which inhibit the activity of the SCN6 polypeptide of Group VI, and the agents which inhibit the expression of the SCN6 polynucleotide or polypeptide of Group VII, are structurally and functionally different chemical compounds, each of which can be made and used without the other compound. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Election of Species

3. This application (*Groups I and II*) contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species 1: cervical cancer

Species 2: colon cancer

Species 3: renal cancer

Species 4: lung cancer

Species 5: uterine cancer

Species 6: breast cancer

Species 7: pancreatic cell carcinoma

Species 8: lymphoma

Species 9: leukaemia

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

Species 1: Claims 15 and 19-21
Species 2: Claims 15 and 19-21

Species 3: Claims 15 and 19-21
Species 4: Claims 15 and 19-21
Species 5: Claims 15 and 19-21
Species 6: Claims 15 and 19-21
Species 7: Claims 15 and 19-21
Species 8: Claims 15 and 19-21
Species 9: Claims 15 and 19-21

The following claim(s) are generic: 1, 2, 10, 14, and 16-18.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are distinct medical conditions having different etiologies and effects, and therefore cannot constitute a unifying technical feature.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.
November 3, 2006

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud

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 Score = 1182 bits (3057),  Expect = 0.0
 Identities = 613/620 (98%), Positives = 615/620 (99%), Gaps = 1/620 (0%)

Query  1    MATKEKLQCLKDFHKDMVKPSPGKSPGTRPEDEAEGKPPQREKWSSKIDFVLSVAGGFVG  60
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Sbjct  30   MATKEKLQCLKDFHKDILKPSPGKSPGTRPEDEAEGKPPQREKWSSKIDFVLSVAGGFVG  89

Query  61   LGNVWRFPYLCYKNGGGAFLIPYFIFLFGSGLPVFFLEIIIGQYTSEGGITCWEKICPLF  120
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Query  121  SGIGYASVVIVSLLNVYYIVILAWATYYLFQSFQKELPWAHCNHSWNTPHCMEDTMRKNK  180
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Query  241  STGKVVYFTATFPFAMXXXXXXXXXXXPGAGRGIKFYLYPDITRLEDPQVWIDAGTQIFF  300
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Query  301  SYAICLGAMTSLGSYNKYKYNSYRDCMLLGCLNSGTSFVSGFAIFSILGFMAQEQGVDIA  360
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Query  421  FLRKGYRREIFIAFVCSISYLLGLTMVTEGGMYVFQLFDYYAASGVCLLWVAFFECFVIA  480
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Query  600  RTVMNGALVKPTHIIVETMM  619
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Sbjct  630  RTVMNGALVKPTHIIVETMM  649


CPU time:      0.03 user secs.       0.00 sys. secs          0.03 total secs.

Lambda      K      H
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Gapped
Lambda      K      H
   0.267   0.0410    0.140

Matrix: BLOSUM62
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